Advisory Circular

Subject: Issuance of Production Approvals Under Subparts G, K, and O

Date: [Type the date here.]

AC No: 21-PAH

Initiated by: AIR- 200

1. PURPOSE. This advisory circular (AC) provides information concerning Subparts G, K, and O of Title 14 Code of Federal Regulations (14 CFR) part 21, Certification Procedures for Products and Parts (part 21). This AC provides an acceptable means, but not the only means, for compliance with the requirements of the new part 21 rule. Implementation of the new part 21 is required within eighteen (18) months of the final rule. However, those applicants for a production approval and current Production Approval Holders (PAH) who so choose may begin operating to the new part 21 rule upon signing of the final rule.

2. CANCELLATION. The following documents will be cancelled eighteen (18) months after the effective date of the new part 21 rule. Until such time, applicants and PAHs may choose to utilize AC 21-PAH or the below listed documents as necessary.

a. AC 21-1B, Production Certificates.

b. AC 21-20B, Supplier Surveillance Procedures.

c. AC 21-27, Production Certification Multinational/Multi-corporate Consortia.

d. AC 21-33, Quality Assurance of Software used in Aircraft or Related Products.

e. AC 21-35, Computer Generated/Stored Records.

f. AC 21-36, Quality Assurance Controls for Product Acceptance Software.

g. Best Practice for Direct Shipment.

h. Best Practice for Internal Quality Audit Program.

i. Best Practice for Scrap or Salvageable Aircraft Parts and Materials.

j. Best Practice for Statistical Quality Control.

k. Best Practice Memorandum on Nondestructive Evaluation Reliability Guidance.

3. RELATED READING MATERIAL.

a. Title 14 CFR part 21, Certification Procedures for Products and Parts.

b. Order 8100.7, Aircraft Certification Systems Evaluation Program.

c. Order 8110.4, Type Certification.

d. Order 8100.10, Requesting Conformity Inspections at a Supplier Outside a Geographic Area.

e. Order 8100.11, Developing Undue Burden and No Undue Burden Decision Papers Under 14 CFR Part 21.

f. Order 8110.42, Parts Manufacturer Approval Procedures.

g. Order 8120.2, Production Approval and Certificate Management Procedures.

h. Order 8120.11, Disposition Of Scrap Or Salvageable Aircraft Parts And Materials.

i. Order 8120.12, Production Approval Holder Use Of Other-Parties To Supplement Their Supplier Control Program.

j. Order 8120.13, International Cooperative Supplier Surveillance Program Procedures.

k. Order 8130.21, Procedures for Completion and Use of FAA Form 8130-3, Airworthiness Approval Tag.

l. AC 21-18, Bilateral Airworthiness Agreements.

m. AC 21-23, Airworthiness Certification of Civil Aircraft, Engines, Propellers, and Related Products Imported to the United States.

n. AC 21-24, Extending a Production Certificate to a Facility Located in a Bilateral Airworthiness Agreement Country.

o. AC 21-29, Detecting and Reporting Suspected Unapproved Parts.

p. Society of Automotive Engineers (SAE) Aerospace Standard (AS) 9100 Quality Management Systems – Aerospace Requirements.

q. SAE Aerospace Recommended Practice (ARP) 9114 Direct Ship – Recommended Practices for Aerospace Companies issued 2005-09-09.

r. SAE AS9102 – First Article Inspection revised 2004-01-13.

s. SAE ARP9134 – Supply Chain Risk Management Guideline issued 2004-03-03.

4. DEFINITIONS. For the purposes of this document, the following definitions apply.

a. Airworthiness approval. Airworthiness approval means a certification that an item conforms to approved design data and is in a condition for safe operation.

b. Article. Article means a material, part, component, process, or appliance.

c. Product. Product means an aircraft, aircraft engine, or propeller.

d. Production approval. Production approval means –

(1) A production certificate;

(2) An approval to produce an article under a Technical Standard Order (TSO) authorization or Parts Manufacturer Approval (PMA).

e. Licensing agreement. Licensing agreement means a commercial agreement between a Type Certificate or Supplemental Type Certificate Holder and a Production Approval Holder/Production Organization Approval Holder (or applicant) formalizing the rights and duties of both partners to use the design data for the purpose of manufacturing the product or part.

f. Quality escape. Quality escape means a product or article that has been released from the quality system, and that does not conform to the applicable design data or quality system requirements.

g. Quality System: An organizational structure with responsibilities, procedures, processes, and resources that implement a management function to determine and enforce quality principles. A Quality System encompasses Quality Assurance and Quality Control.

(1) Quality Assurance: A management system for programming and coordinating the quality maintenance and improvement efforts of the various groups in a design and/or manufacturing organization, so as to permit design and/or production in compliance with regulatory and customer requirements.

(2) Quality Control: Conduct and direct supervision of the quality tasks (inspection of product) to ensure that the quality requirements of the product are achieved.

h. Standard Part: A part that is manufactured in complete compliance with an established government or industry-accepted specification, which contains design, manufacturing, and uniform identification requirements. The specification must include all information necessary to produce and conform the part, and must be published so that any person/organization may manufacture the part.

Note: Examples of specifications include, but are not limited to National Aerospace Standards (NAS), Air Force-Navy Aeronautical Standard (AN), Society of Automotive Engineers (SAE), SAE Aerospace Standard (AS), Military Standard (MS), etc.

5. DISCUSSION. This AC covers all sections of 14 CFR part 21, Subpart G, Production Certificates (PC), Subpart K, Parts Manufacturer Approval (PMA), and Subpart O, Technical Standard Order (TSO) Authorization. While some sections are self-explanatory, other sections require further discussion, information, and examples. The headings of each of the following main paragraphs are in chronological order per the regulation. However, some headings have more than one section referenced. The sections of part 21 are designed to address both new applicants for a production approval, and current PAHs, respectively.

a. Applicability. Sections 21.131, 21.301, and 21.601 prescribe the procedural requirements for issuing production approvals (PC/PMA/TSO) and the rules governing the holders of those production approvals. Section 21.601 also includes procedural requirements for issuing letters of TSO design approval. Those individuals that are interested in obtaining a production approval should begin by determining which type of production approval they are seeking.

b. Eligibility. Section 21.132 prescribes who is eligible for a production certificate. In determining basic eligibility, individuals must hold, for the product concerned, a current type certificate, a supplemental type certificate, or the rights to the benefits of that type certificate or a supplemental type certificate under a licensing agreement. After determining basic eligibility, individuals are advised to review the regulatory requirements for production certificate holders in order to determine if they can meet those requirements.

c. Application. Sections 21.133, 21.303, and 21.603 prescribe that an applicant for a production approval must apply in a form and manner prescribed by the FAA. Sections 21.303 and 21.603 also require the applicant to provide additional information along with the application. Applicants should refer to the section for the type of production approval that they wish to obtain in order to ensure that they can meet all of the applicable requirements.

(1) In the case of a PC, an applicant must submit FAA Form 8110-12, Application for Type Certificate, Production, Certificate, or Supplemental Type Certificate to the Manager, Manufacturing Inspection Office (MIO), in the directorate in which the applicant's principal manufacturing facility is located.

(2) In the case of a PMA, an applicant must submit a letter of application to the Aircraft Certification Office (ACO) in the geographical area in which the applicant's manufacturing facility is located. However, if the applicant is applying on the basis of an STC or identicality by licensing agreement, the application will be sent to the geographic Manufacturing Inspection District Office (MIDO).

(3) In the case of a TSO authorization, an applicant must submit a letter of application to the ACO in the region in which the applicant's principal manufacturing facility is located.

d. Organization. Sections 21.135, 21.305, and 21.605 prescribe a requirement that each applicant must provide the FAA with a document describing how the applicant's organization will ensure compliance with the provisions of the applicable subpart. At a minimum, the document must describe assigned responsibilities and delegated authority, and the functional relationship of those responsible for quality to management and other organizational components.

(1) While the FAA understands the need for various business models and organizational structures, the intent of this requirement is to obtain a commitment from the top management to –

(a) Establish a quality system that complies with the applicable subchapter and ensures that each product and article conforms to its approved design and is in a condition for safe operation; and

(b) Continually improve that quality system.

e. Quality system. Section 21.137 prescribes a requirement that each applicant must establish and describe in writing a quality system that ensures that each product and article conforms to its approved design and is in a condition for safe operation. Sections 21.307 and 21.607 prescribe that an applicant establish a quality system that meets the requirements of section 21.137. The quality system includes the following fourteen elements:

(1) Design data control. Section 21.137(a) requires procedures for controlling design data and subsequent changes to ensure that only current, correct, and approved data is used.

(a) Applicants for a production approval should have procedures for design data control that provide for storing, maintaining, and protecting design data. PAHs should ensure that design data is identified, controlled, and made available to those persons who require them. There should be procedures for approving, documenting, and controlling changes to the design data.

(b) Minor design changes should be approved by a method acceptable to the FAA. Major design changes, including changes to manufacturing and special process specifications, must be submitted to and approved by the FAA. Design changes necessary to correct unsafe conditions should be incorporated into the FAA-approved design. Instructions for Continued Airworthiness (ICA) should be kept current with the design changes.

(2) Document control. Section 21.137(b) requires procedures for controlling quality system documents and data and subsequent changes to ensure that only current, correct, and approved documents and data are used.

(a) Applicants for a production approval should have procedures for quality system document/data control that provide for storing, maintaining, and protecting the documents/data.

(b) PAHs should ensure that quality system documents/data, to include all tags and forms, are identified, controlled, and made available to those persons who require them.

(c) There should be procedures for approving, documenting, and controlling changes to the quality system documents/data.

(d) Applicants and PAHs may choose to store documents electronically, as long as hard copies are made available as necessary.

(3) Supplier control. Section 21.137(c) requires procedures that ensure that each supplier-furnished product or article conforms to its approved design; and requires each supplier to report to the

production approval holder if a product or article has been released from that supplier and subsequently found not to conform to the applicable design data.

(a) Appendix 1 provides additional information on what procedures a typical supplier control program should contain.

(b) The PAH is reminded that they are ultimately responsible for the determination that all products and articles conform to their approved type design and are in condition for safe operation. This responsibility cannot be subjugated to or relieved by the use of approved suppliers, risk and revenue sharing partners, co-producers, etc.

(4) Manufacturing process control. Section 21.137(d) requires procedures for controlling manufacturing processes to ensure that each product and article conforms to its approved design.

(a) Applicants for a production approval should have procedures for ensuring that all manufacturing processes, including special processes, are identified and defined by FAA-approved design data and detailed in process specifications. PAHs should ensure that work instructions and revisions to work instructions are reviewed, approved, controlled, documented, and made available to those persons who require them. Any new or changed processes should be substantiated and approved by appropriate personnel. Traceability should be maintained through the manufacturing process from raw material to completed product/article. Articles that are introduced into production prior to full acceptance should have a process for identifying, controlling, and segregating them.

(b) Airborne and production software present unique difficulties in manufacturing process control. PAHs that manufacture airborne software may obtain additional guidance from the Society of Automotive Engineers (SAE), Aerospace Standard 9106, Deliverable Aerospace Software Supplement for AS9100A. PAHs that utilize production software for the design, manufacture, inspection, test, acceptance, or calibration of a deliverable product may obtain additional guidance from SAE, Aerospace Recommended Practice 9005, Aerospace Guidance for Non-Deliverable Software.

(5) Inspecting and testing. Section 21.137(e) requires procedures for inspections and tests used to ensure that each product and article conforms to its approved design. These procedures must include the following, as applicable: a flight test of each aircraft produced unless that aircraft will be exported as an unassembled aircraft; and a functional test of each aircraft engine and each propeller produced.

(a) Applicants for a production approval should have procedures that document inspection methods for each product/article in order to ensure that products/articles conform to their FAA-approved design data. Procedures should provide methods of marking/traceability that ensure identification of inspection status throughout the manufacturing process. Also, procedures should ensure inspection marking devices and stamps are only issued to authorized persons and are controlled.

(b) Test procedures/instructions and subsequent changes to those procedures/instructions should be established, maintained, and adequately controlled. PAHs should ensure that the appropriate organizations participate in the review of test instructions or procedures. Products/articles that have been adjusted or reworked after test acceptance should be retested using approved processes.

(c) Any use of statistical sampling should include sampling plans that are appropriate for the type of product being accepted, and personnel should be trained in statistical sampling techniques. Engineering and manufacturing organizations should participate in the review, implementation, and maintenance of statistical quality/process control techniques used for product acceptance. PAHs may choose to utilize the Society of Aerospace Engineers (SAE) Aerospace Recommended Practice (ARP) 9013, Statistical Product Acceptance Requirements, which established general requirements when implementing any of the following statistical product acceptance methods:

1 ARP9013/1, Statistical Product Acceptance Requirements Using Isolated Lot Sampling Methods;

2 ARP9013/2, Statistical Product Acceptance Requirements Using Attribute or Variable Lot Acceptance Sampling Plans;

3 ARP9013/3, Statistical Product Acceptance Requirements Using Process Control Methods; or

4 ARP9013/4, Statistical Product Acceptance Requirements Using Continuous Sampling, Skip-Lot Sampling, or Methods for Special Classes.

(d) Should the PAH decide to utilize it, Aerospace Recommended Practice (ARP) 9013, Statistical Product Acceptance Requirements also establishes the minimum content required to be covered in a PAH's documented procedures governing the application of statistical product acceptance methods as chosen by the PAH. This document does not apply to statistical methods that are separate from product acceptance. Many companies use excellent statistical methods solely to monitor and improve their product quality, and those methods are not subject to the requirements of this document. This document series applies only to those statistical methods used for product acceptance.

(e) PAHs that utilize non-destructive testing to verify conformity of products/articles should have procedures that address acceptance and rejection criteria. Adequate test pieces with known defects should be available to Non-Destructive Inspection (NDI) personnel. PAHs should also have procedures that address certifying, recertifying, and de-certifying of non-destructive testing personnel. PAHs may choose to utilize National Aerospace Standard NAS 410, NAS Certification and Qualification of Nondestructive Testing Personnel.

(f) PAHs who manufacture a complete aircraft should ensure that flight test procedures and subsequent changes are submitted to and approved by the FAA. Flight test pilots should be fully qualified, and flight check-off lists should be properly completed.

(6) Inspection, measuring, and test equipment control. Section 21.137(f) requires procedures to ensure calibration and control of all inspection, measuring, and test equipment used in determining conformity of each product and article to its approved design. Each calibration standard must be traceable to a standard acceptable to the FAA.

(a) Applicants for a production approval should have procedures that ensure that tools, gauges and equipment are approved, periodically inspected, and calibrated. Standards used for

calibration should have adequate accuracy and be traceable to an FAA recognized international standards organization. Any equipment required for special processing, such as tools, gauges, instruments, timers, etc. should be available and calibrated.

(b) PAHs should have a tool control procedure to ensure that tools and gauges, including NDI equipment, are protected, maintained, and used in an acceptable environment. Procedures should ensure that, when a product or article has been accepted by an out of tolerance gauge, an evaluation is conducted to determine the need for corrective action.

(7) Inspection and test status. Section 21.137(g) requires procedures for documenting the inspection and test status of products and articles supplied or manufactured to the approved design.

(a) Applicants for a production approval should have procedures that define how inspection and test records are generated and maintained. PAHs should ensure that the receiving inspection department verifies that supplier-furnished articles/service conform to the FAA-approved design data and/or purchase order requirements, and records of receiving inspection should be generated and maintained.

(b) The inspection status of production products/articles should be identifiable throughout the manufacturing cycle. Records of completed tests for aircraft, engines, or propellers should be generated and maintained.

(8) Certifying staff. Section 21.137(h) requires procedures for establishing and maintaining a certifying staff responsible for issuing airworthiness approvals for each aircraft engine, propeller, and article.

(a) Applicants for a production approval should have procedures that include the method used for selecting, training, appointing, removing, and terminating certifying staff members, to include a review of individuals' qualification, background, experience, and training.

(b) The PAH's certifying staff should be appointed and documented, and their roles and responsibilities should be defined prior to the issuance of airworthiness approvals. Appendix 2 provides additional information on establishing and maintaining a certifying staff.

(9) Nonconforming product and article control. Section 21.137(i) requires procedures to ensure that only products or articles that conform to their approved design are installed on a type-certificated product. These procedures must provide for the identification, documentation, evaluation, segregation, and disposition of nonconforming products and articles. Only authorized individuals may make disposition determinations. Section 21.137(i) also requires procedures to ensure that discarded articles are rendered unusable.

(a) Applicants for a production approval should have procedures that ensure that a material review board (MRB) is established, documented, and is operational. PAHs should have procedures that include how nonconforming products/articles are identified, controlled, and dispositioned.

(b) Engineering should review nonconforming material to determine if acceptance of the nonconformance constitutes a major or minor change to FAA-approved data. The FAA, through the design approval process, should approve any MRB disposition identified as a major change.

(c) Upper management should review and analyze nonconforming material data to detect adverse trends and determine appropriate levels of corrective and preventive actions.

(d) Scrap and salvageable aircraft products and articles should be disposed of in an acceptable manner. Appendix 3 provides additional information on controlling and dispositioning scrap and salvageable aircraft products and articles.

(10) Corrective and preventive actions. Section 21.137(j) requires procedures for implementing corrective and preventive actions to eliminate the causes of an actual or potential nonconformity to the approved design or noncompliance with the approved quality system.

(a) Corrective action: Applicants for a production approval should have procedures to eliminate the cause of known nonconformities and/or noncompliances in order to prevent recurrence. Corrective actions should be appropriate to the effects of the nonconformities and/or noncompliances encountered and should address the following:

1 Review of nonconformities and/or noncompliances;

2 Determination of the cause(s) of nonconformities and/or noncompliances;

3 Evaluating the need for action to ensure that nonconformities and/or noncompliances do not reoccur;

4 Determination of action(s) needed and implementation of those actions;

5 Recording of the results of action(s) taken;

6 Review of corrective action(s) taken; and

7 Flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause.

(b) Preventative action: Applicants for a production approval should have procedures to eliminate the cause of potential nonconformities and/or noncompliances in order to prevent their occurrence. Preventive actions should be appropriate to the effects of the potential problems and should address the following:

1 Determining potential nonconformities/noncompliances and their causes;

2 Evaluating the need for action to prevent occurrence of nonconformities/ noncompliances;

3 Determining and implementing action needed;

4 Recording of results of action taken; and

5 Reviewing preventive action taken.

(c) PAHs should monitor the response to, implementation of, and effectiveness of corrective and preventative actions when processes or procedures result in nonconforming products or articles.

(11) Handling and storage. Section 21.137(k) requires procedures to prevent damage and deterioration of each product and article during handling, storage, preservation, packaging, and delivery.

(a) Applicants for a production approval should have procedures that ensure that only conforming and properly identified products/articles are placed in storage, ensure traceability for split lots, and ensure that removal/issuance of those products/articles is controlled.

(b) PAHs should have procedures that ensure that any special environmental controls are observed during material storage, handling, manufacturing, and assembly of products/articles. Age sensitive products/articles should be identified and controlled. There should be proper separation and identification of products/articles in storage and manufacturing areas. Only conforming and properly identified products/articles should be shipped under the production approval.

(12) Control of quality records. Section 21.137(l) requires procedures for identifying, storing, protecting, retrieving, retaining, and destruction of quality records. A production approval holder must retain these records for at least 5 years for the products and articles manufactured under the approval and at least 10 years for critical components identified under § 45.15(c).

(a) Applicants for a production approval should establish a record retention schedule for various types of process, test, and quality/inspection system data.

(b) PAHs should include inspection and test records, supplier records, special process certifications, material review board records, and production travelers in the quality records to be retained. Records should be legible, complete, and accurate. Any storage media used for record retention should exhibit legible data, acceptance stamps, and signatures, as required, and should be FAA approved prior to implementation.

(13) Internal audits. Section 21.137(m) requires procedures for planning, conducting, and documenting internal audits to ensure compliance with the approved quality system. The procedures must include reporting results of internal audits to the manager responsible for implementing corrective and preventative actions.

(a) Applicants for a production approval should have procedures that establish an internal audit program. The internal audit program should verify compliance with established policies, procedures, and approved data.

(b) PAHs should ensure that the results of internal audits are reported to the appropriate level of management, and that audits are used for improvement of the quality system/product. Appendix 4 provides additional information on internal audit programs.

(14) In-service feedback. Section 21.137(n) requires procedures for receiving and processing feedback on in-service failures, malfunctions, and defects. These procedures must include a process for assisting the design approval holder to address any in-service problem involving design changes; and determine if any changes to the Instruction for Continued Airworthiness are necessary.

(a) Applicants for a production approval should have procedures that establish a system for receiving, processing, and tracking of in-service failures, to include how records are generated and maintained.

(b) PAHs should ensure that service problems, unairworthy conditions, unsafe features and unsafe characteristics reported by the FAA or users are investigated and prompt corrective actions are taken.

(c) Service bulletins and changes to maintenance manuals should be approved by authorized personnel and coordinated with FAA engineering.

(d) Users of products/articles should be notified when those products/articles are recalled for suspected or known nonconformance. The FAA should be notified per § 21.3, Reporting of failures, malfunctions, and defects.

(15) Quality escapes. Section 21.137(o) requires procedures for identifying, analyzing, and initiating appropriate corrective action for products or articles that have been released from the quality system and that do not conform to the applicable design data or quality system requirements.

(a) Applicants for a production approval should have procedures that document how they will track, evaluate, categorize, and disposition all nonconforming products/articles, to include actions to correct deficiencies in the quality system that allowed for the quality escape.

(b) PAHs should utilize trend analysis and risk assessment tools to determine the severity of, and long-term effects of nonconformances.

f. Quality system documentation. Sections 21.138, 21.308, and 21.608 prescribe a requirement that each applicant must provide a manual describing its quality system to the FAA for approval. The manual must be in the English language and retrievable in a form acceptable to the FAA.

(a) If the quality manual is stored digitally through a computer-based medium, it should be easily available to Production Approval Holder (PAH) and FAA personnel who need to use the documentation for performing their duties.

(b) Applicants are reminded that the manual must address each of the requirements listed under the quality system above.

g. Location of manufacturing facilities. Sections 21.139, 21.309, and 21.609 state that, if FAA finds no undue burden in administering the applicable requirements of Title 49 U.S.C. and the applicable subchapter, an applicant may obtain a production certificate for manufacturing facilities located outside of the United States. Further, the PAH must obtain FAA approval before making any changes to its manufacturing facilities that could affect the inspection or airworthiness of its products or articles, including changes to the location of any of its manufacturing facilities. Therefore, this type of change must be approved in accordance with sections 21.150(b), 21.320(b), and 21.620(b), respectively.

h. Inspections and tests. Sections 21.140, 21.310, and 21.610 prescribe requirements that each applicant for or holder of a production approval must allow the FAA to inspect its quality system, facilities, technical data, and any manufactured products or articles, and witness any tests, including any inspections or tests at a supplier facility, necessary to determine compliance with the applicable subchapter. Section 21.310 also prescribes prohibitions unique to that section. Applicants should refer to the applicable section in order to ensure that they are not in violation of those prohibitions.

i. Issuance. Sections 21.141, 21.311, and 21.611 prescribe that the FAA issues a production approval after finding that the applicant complies with the requirements of the applicable subchapter.

(1) Applicants should ensure that they have reviewed and/or documented how they have met the applicable requirements in order to ensure a timely review by the FAA.

(2) Applicants for a production certificate that are a multinational and/or multi-corporate consortium may refer to Appendix 5 of this AC to ensure that they have a quality system that meets the requirements of § 21.137.

j. Production limitation record (PLR). Section 21.142 prescribes that the FAA issues a production limitation record as part of a production certificate. The record lists the type certificate number and the model of every product that the production certificate holder is authorized to manufacture. Applicants for a production certificate should ensure that the PLR accurately reflects the products that they wish to manufacture.

k. Duration. Sections 21.143, 21.313, and 21.613 prescribe that a production approval is effective until surrendered, suspended, revoked, or terminated by the FAA. Minor differences exist between the duration of a PC and that of a PMA or TSO authorization. Applicants receiving a production approval should refer to the applicable section for accurate information on the duration of a particular production approval. Section 21.613 also prescribes that, if a TSO is revised or canceled, the holder of an effected FAA letter of acceptance of a statement of conformance, TSO authorization, or letter of TSO design approval may continue to manufacture articles that meet the original TSO with obtaining a new acceptance, authorization, or approval but must comply with the requirements of §§ 21.3, 21.137(1), 21.610, 21.613 through 21.619, and 45.15(b).

l. Transferability. Sections 21.144, 21.314, and 21.614 prescribe that the holder of a production approval may not transfer the production approval.

(1) While there are no provisions for transferring a production approval, the FAA recognizes that companies change hands frequently. In many cases, design data, quality systems, and manufacturing processes are all transferred as part of the sale. Therefore, the FAA does support efforts to fast-track and establish a new production approval.

(2) Applicants for new production approvals that are based on previously established production approvals should consult with their local Aircraft Certification Office and Manufacturing Inspection Office for assistance as soon as possible.

m. Privileges. Section 21.145 prescribes privileges associated with a production certificate. Applicants for a production certificate should refer to the applicable section in order to ensure that they understand what privileges are included with that type of production approval.

n. Responsibility of holder. Sections 21.146, 21.316, and 21.616 prescribe what the holder of a production approval must do. Applicants should refer to the section for the type of production approval that they wish to obtain in order to ensure that they understand all of the applicable requirements.

(1) The holder of a production approval has a basic responsibility for controlling the manufacture of completed products and articles in conformity with the FAA-approved type design data and quality system requirements. This responsibility cannot be subjugated to or relieved by the use of approved suppliers, risk and revenue sharing partners, co-producers, etc. Although this responsibility never changes, the PAH may be relieved of some of the burden of inspection and testing duties when it-

(a) Uses type certificated products or articles manufactured under another person's production approval; and

(b) Demonstrates through historical data a high level of confidence (e.g., low risk, consistently conforming articles/materials, zero quality escapes, etc.).

o. Amendment of the production certificates. Section 21.147 prescribes that the holder of a production certificate must apply for an amendment to a production certificate in a form and manner prescribed by the FAA. The applicant for an amendment to a production certificate to add a type certificate or model, or both, must comply with the applicable requirements of §§ 21.137, 21.138, and 21.150. Currently, the method of applying for an amendment is a properly executed FAA Form 8110-12, Application for Type Certificate, Production Certificate, or Supplemental Type Certificate.

p. Approval for deviation. Section 21.618 prescribes that each manufacturer who requests approval to deviate from any performance standard of a TSO must show that factors or design features providing an equivalent level of safety compensate for the standards from which a deviation is requested. The manufacturer must send requests for approval to deviate, together with all pertinent data, to the appropriate aircraft certification office. If the article is manufactured under the authority of a foreign country or jurisdiction, the manufacturer must send requests for approval to deviate, together with all pertinent data, through the civil aviation authority of that country or jurisdiction to the FAA.

q. Design changes. Sections 21.319 and 21.619 prescribe what constitutes a major or minor design change, as well as who may make those changes. Minor changes must be approved under a method acceptable to the FAA. The FAA must approve any major changes prior to inclusion in the design of the product or article. Production approval holders who are not sure if a design change is major or minor should consult with the FAA prior to implementing the changes. Additional requirements and/or prohibitions are included in the applicable section. Applicants for a production approval should refer to those sections to ensure that they understand the requirements and/or prohibitions.

r. Changes in quality system. Sections 21.150, 21.320, and 21.620 prescribe requirements that each change to the quality system is subject to review by the FAA; and the holder of a production approval must immediately notify the FAA, in writing, of any change that may affect the inspection, conformity, or airworthiness of its product or article. Production approval holders who wish to initiate changes to the quality system should submit the proposed changes to the Manufacturing Inspection Office with certificate management responsibilities.

s. Issuance of letters of TSO design approval: import articles. Section 21.621 prescribes under what conditions a letter of TSO design approval may be issued for imported articles. Applicants should refer to this section in order to ensure that they can meet all of the applicable requirements.

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Appendix 1
Supplier Control Program

1. PURPOSE. This document provides information and describes criteria for establishing and maintaining a supplier control program. Production Approval Holders may use this document in support of their responsibilities under §§ 21.137, 21.307, and 21.607.

2. BACKGROUND. Part 21 requires applicants to establish a quality system as a prerequisite to the issuance of an FAA production approval and to maintain this system after the approval has been issued. Part 21 also requires that the PAH's quality system provide a means to determine that supplier-produced components (e.g., software, articles, and subassemblies), or services (e.g., special processes, calibration, etc.), and customer / buyer furnished equipment or material conform to FAA-approved design data and are in condition for safe operation.

3. GENERAL DISCUSSION.

a. A PAH's system must ensure that all articles and services furnished by its suppliers, including sub-tier suppliers, conform to the PAH's approved design data. The PAH is responsible for supplier adherence to requirements flowed down through the supplier chain. In this regard, a PAH does not "delegate" responsibility under its production approval to a supplier; the PAH remains responsible under Title 49, United States Code, and the regulations, for the airworthiness of each product, article, or service provided by a supplier.

b. A PAH who plans to utilize a supplier (including sub-tier suppliers) in a non-U.S. jurisdiction should notify the FAA as soon as possible to determine the FAA's ability to support the program. PAH's may use suppliers on a global basis when the PAH has established and implemented a supplier control system acceptable to the FAA. With sufficient prior notice, the FAA can work with the PAH to resolve potential conflicts, and prevent the possibility of delayed programs. The PAH and the FAA will coordinate to ensure there is no undue burden in the use of global suppliers.

c. The PAH is responsible for establishing, and imposing, requirements for suppliers to report all undocumented nonconforming articles which may have left the supplier's quality system. This reporting shall be to the PAH.

d. To ensure that all articles and services furnished by its suppliers, including sub-tier suppliers, conform to the applicable design data, the PAH is responsible for adequate quality requirements for its suppliers, depending on the nature of the relevant supplied items and the supplier (suppliers holding their own production approvals, or suppliers without their own production approval). However, the PAH does not delegate responsibility under it's production approval to a supplier.

e. The PAH is responsible for determining and applying acceptance standards for physical condition, configuration status, and conformity of supplied products and articles (including Buyer Furnished Equipment) whether to be used in production or delivered to customers as spare parts.

f. The PAH is responsible to control the standard of supplied raw/consumable materials, standard parts, and services such as special processes (e.g., non-destructive testing or inspections, heat treatment, surface finishing, and shot peening), which are included in the approved design data.

g. The FAA does not "approve" suppliers, but may conduct surveillance of the supplier control system at both the PAH and supplier facilities in accordance with FAA Order 8120.2, Production Approval and Certificate Management Procedures. The FAA may also employ a participating Civil Aviation Authority (CAA) or National Aviation Authority (NAA) to act on behalf of the FAA in carrying out FAA duties. FAA or CAA/NAA surveillance may include evaluations conducted in accordance with the Aircraft Certification Systems Evaluation Program (ACSEP), Supplier Control Audits, or via other surveillance methods available to the FAA. The PAH may not rely on FAA or CAA/NAA surveillance as a means of supplier control.

4. ELEMENTS OF A SUPPLIER CONTROL PROGRAM. A PAH is responsible for ensuring that each product, or article thereof, conforms to the FAA-approved design data and is in a condition for safe operation. This responsibility remains the same whether the PAH produces the entire product or articles at its facility, or utilizes suppliers to furnish related articles or services. The quality system of the PAH needs an organizational structure, appropriate supplier arrangements, and procedures to adequately control suppliers. It must be defined in a manual and be FAA approved. Its implementation and maintenance is subject to evaluation by the FAA. FAA production approvals are based upon the ability of the quality system to ensure production of conforming products or articles thereof. Therefore, the supplier control program should contain procedures that include:

a. An organizational structure that ensures appropriate authority and sufficient resources, as well as adequate expertise to control supplier activities.

b. A supplier arrangement that is documented through a contract, and which defines all necessary elements and procedures between the PAH holder and a supplier. Attachment 1, "PAH – Supplier Arrangement", contains the minimum mandatory elements to be defined in the arrangement between the PAH and the supplier.

c. A process that evaluates and selects suppliers based on their capability to perform all manufacturing activities, inspections, and tests necessary to determine conformity of articles to the applicable design data, and the ability to meet the specified requirements. The selection and evaluation process may use the same techniques as described in 4.e. There should be criteria for selection, evaluation, re-evaluation and disapproval of suppliers. These include:

(1) Initial evaluation of suppliers to determine their capability to meet requirements. The PAH should make this determination prior to permitting the supplier to furnish any articles or services.

(2) Periodic evaluations to ensure continued adherence to the requirements.

(3) Methods for determining:

(a) The extent of the evaluations, dependent, as a minimum, on the type, complexity, method of control, and importance of products, articles, or services procured; and

(b) On-site evaluation, process reviews, document reviews, or independent product evaluations.

d. Suppliers under the PAH quality system are included in or referenced to a controlled list together with their associated scope. Procedures ensure that purchase documentation is issued only to suppliers on this list.

e. Description of the means of supplier control, which may be based upon use of the following techniques as appropriate to the system or product orientation necessary to ensure conformity, and as applicable for the concerned organization. The techniques described below are not all-inclusive, and are provided to assist the PAH in developing its supplier control procedures.

(1) Risk assessment: takes into account the combination of supplier and product risk factors. Product risk factors include safety classification from the design approval process, special process and design and manufacturing complexity. SAE ARP9134 "Supply Chain Risk Management Guideline" issued 2004-03-03 is an industry guideline that has been reviewed by the FAA and found acceptable to provide guidance for the identification of supplier risk factors.

(2) Qualification and auditing of supplier's quality system.

(3) Monitoring continued capability throughout the supply chain in performing all manufacturing activities, inspections and tests necessary to determine conformity of products or articles to applicable design data.

(4) First article inspection, including destruction (destructive testing) if necessary, to verify that the article conforms to the approved data for a new production line, changes to the manufacturing/quality process or new supplier. SAE AS9102 "First Article Inspection" is an industry standard that has been reviewed by the FAA and found acceptable to provide guidance in the establishment of first article processes and procedures.

f. Methods for verifying supplier product, articles, software and services conform to specified requirements. This includes customer supplied materials and customer-designated sources. These include but are not limited to the following:

(1) For articles/services accepted at the PAH's facility, inspection may be accomplished upon receipt or, when characteristics remain accessible, at any time prior to the final acceptance of the end product or part thereof. The procedures should encompass a complete inspection of each part including, as appropriate for the particular article/service furnished, all dimensional characteristics, non-destructive testing, hardness checks, spectrographic analysis, functional tests, etc. When the PAH has established that the supplier's production/process methods will consistently produce articles or services that conform to the approved design data, statistical quality control methods may be acceptable. The inspection plan that is used for acceptance of articles must preclude the acceptance of any nonconforming articles. In addition, when necessary to determine material integrity, the following methods should be considered:

(a) Laboratory analysis for complete chemical and physical properties to be performed on each article when such tests can be performed without destroying the article (e.g., by test coupon, small section of the article, etc.).

(b) When laboratory analysis of articles cannot be performed without destroying the articles, a sample of such items should be subjected to a qualitative and quantitative analysis to verify complete chemical and physical properties.

(2) For article/services that cannot or will not be inspected upon receipt, the PAH's procedures should include, as a minimum, inspection and testing of first articles to verify that the articles conform to the approved design data and periodic inspection thereafter. This may be accomplished at the supplier facility when the PAH can show that such inspections and tests will be accomplished under controlled conditions acceptable to the FAA. More than one article may require such inspection or testing until the production repeatability of the supplier has been established. Methods used to segregate articles awaiting certification. These procedures should include methods to control, identify, and segregate articles waiting for testing or inspection from those already approved.

(3) The PAH may allow a supplier to perform an appropriate inspection/major inspection when it has established that the supplier is capable of performing such inspection function, however, any delegation of inspection or use of statistical techniques beyond the first tier supplier must be approved by the PAH. Such delegation includes:

(a) Major inspections. These include:

1 Properties classified as critical by the approved design holder's engineering drawings, process specifications, test specifications, and quality control procedures, or

2 Properties that cannot be verified except by destructive test of each item or extensive disassembly.

(b) Material review. Material review requirements include, as a minimum:

1 Identification and maintenance of relevant Material Review Board (MRB) procedures that define the scope and authority of the supplier MRB (e.g., documentation of non-conformances, maintenance of records, members of the MRB, mutilation of "scrap" material).

2 Process for submittal to the PAH of supplier non-conformances that must be approved before being considered changes to the FAA-approved type design.

(4) Requirements for making applicable supplier information available to the FAA upon request. This information should include but is not limited to:

(a) The name and address of each supplier who performs major inspection/material review for the PAH.

(b) The name and address of each supplier who furnishes articles/services where a determination as to conformance to the approved design data cannot, or will not, be made upon receipt at the PAH's receiving facility.

(c) Where, and by whom, the article or service will undergo inspection.

(d) The name, title, and telephone number of the person to contact at the supplier facility who can furnish purchase order(s), quality control data, technical data, and other pertinent data/information to the FAA.

(e) Identification of each supplier authorized to direct ship.

(f) Results of the PAH's supplier evaluations, audits, and/or other surveillance activities.

(5) Method for generating and maintaining receiving inspection records. These procedures should include:

(a) Contents of each record used, including, as a minimum, for the material or product inspected, the name, part number, sample size, type and number of inspections made, conformance or nonconformance, number and description of non-conformances found, and action taken.

(b) Requirements for record legibility, completeness, and accuracy.

(c) Requirements that tape files, microfilm, etc., used for record retention exhibit legible data, acceptance stamps and/or signatures.

g. A supplier rating system, which gives visibility of the performance, capability and reliability of the suppliers.

h. Ensure advance notification to the authority of any significant change in the scope of any supplier arrangements in accordance with an agreed notification procedure to enable the authority to discharge its investigation/surveillance duties.

i. Implementing processes and/or procedures that require suppliers to report all undocumented nonconforming products or articles that may have left the supplier's quality system. This reporting shall be to the PAH and as necessary to the FAA in accordance with Part 21 requirements.

j. Ensure changes in requirements are properly controlled and incorporated as agreed between the supplier and the PAH. These include but are not limited to:

(1) Submittal of supplier designs and changes, to the PAH, for approval prior to incorporation, when required.

(2) Submittal of changes to the PAH of supplier manufacturing process, when required.

(3) Submittal to the PAH of changes to a supplier's quality system that may affect inspection, conformity, or the airworthiness of the product.

(4) Methods used to act upon notifications of nonconforming products, ensuring proper investigation and corrective action is taken.

k. Methods for controlling direct shipments from a PAH's supplier directly to a customer, for articles which have been manufactured under the PAH's production approval. The customer may order articles either from the PAH or the supplier. Society of Automotive Engineers (SAE) Aerospace Recommended Practice (ARP) 9004 "Direct Ship – Recommended Practices for Aerospace Companies" is an industry guideline that has been reviewed by the FAA and found acceptable to provide guidance in the establishment of direct shipment processes and procedures. There may be restrictions on the direct shipment of articles from suppliers not located in the United States. The cognizant FAA Manufacturing Inspection District Office may be contacted for more specific information. Direct shipment may only be used when the PAH:

(1) Has approved quality procedures that will compensate for the absence of inspections normally conducted at the PAH's facility. Compensating factors shall include onsite evaluations of the supplier and the inspection of the article as either:

(a) Source inspection performed by the PAH or

(b) Inspection by the supplier under a delegated inspection authority from the PAH

(2) Provides direct ship authorization to a supplier.

(3) Issues and maintains records of direct ship authorization and makes them available to regulatory authorities upon request.

(4) Ensures the requirements of the importing country will be met prior to authorizing direct shipment to a customer located in a foreign country

(5) Obligates the supplier to:

(a) Direct ship the article

(b) Meet any special customer requirements accepted by the PAH

(c) Maintain evidence that the supplier has direct ship authorization from the PAH

(d) Maintain evidence of direct shipments made on the behalf of the PAH

(e) Provide a signed direct ship declaration with the shipment

(f) Provide a signed/stamped statement of conformance certifying that the article conforms to approved data with the shipment

(g) Provide traceability with the shipment to the customer purchase request

(h) Provide evidence with the shipment that acceptance / inspection has been accomplished by the PAH or through delegated inspection authority

(i) When delegated inspection is used, provide a statement with the shipment that delegation of inspection authority has been granted by the PAH and that the inspection was performed on behalf of the PAH.

l. Method for the use of other-party supplier surveillance as part of a PAH's supplier control program. These processes may be used by a PAH provided:

(1) procedures clearly define the flow-down of requirements to the supplier, and

(2) procedures provide for access to supplier information, and

(3) procedures detail methods for making determinations of supplier acceptability based on the industry shared process, and

(4) the other-party arrangement is documented, makes reference to the Industry other party scheme used (e.g., Industry Controlled Other Party Scheme (ICOP), NADCAP), and referred to in the authority-approved PAH procedures, and

(5) this does not result in delegation of supplier control responsibility and hence the PAH remains responsible for application and direct assessment of any additional regulatory and/or quality/process/product requirements, and

(6) the PAH demonstrates control of the arrangement (e.g., quality standard/technical specification, qualification of auditors, and oversight of the system).

Note: information and results from these shared processes can be the basis for some supplier control aspects of sub-tier suppliers that ultimately provide materials, products, articles, appliances, and services to PAHs via the PAH's suppliers

m. Methods addressing suppliers that hold a production approval for the products, articles or appliances to be supplied. Supplier oversight may be reduced to a level at which a satisfactory interface between the two quality systems can be demonstrated to the authority. Thus, for the purpose of showing conformity, a PAH may rely upon documentation for articles or appliances released under a supplier's own production approval (PAH) privileges provided:

(1) the product/articles to be supplied are included in the scope of approval and the supplier can provide an authorized release certificate , and

(2) if the supplier is not located in the authority country, a bilateral arrangement is in effect covering production matters between the authority and the foreign authority concerned.

n. Methods for the utilization of suppliers (including sub-tier suppliers) outside the United States. These should include provisions for the following:

(1) The PAH shall make available to the FAA information on non-US suppliers when requested.

(2) The PAH should ensure that there are processes, agreements or procedures in place to mitigate any undue burden upon the FAA which would in any way inhibit the FAA from performing certificate management responsibilities.

(3) Assurance of access should be provided to the PAH by both the supplier and, when no regulatory agreements are in place, the government of the jurisdiction in which the supplier is located. This assurance of access should be made available to the FAA.

(4) If access is at any time obstructed or denied, the PAH may be instructed by the FAA to cease using the supplier.

o. When a PAH uses a supplier in a jurisdiction with which the U.S. has a Bilateral Airworthiness Agreement (BAA) or Bilateral Aviation Safety Agreement (BASA) with Implementation Procedures for Airworthiness (IPA), the FAA may utilize a NAA to perform certificate management activities and/or conduct inspections on behalf of the FAA as a means of determining that the PAH is performing its supplier control responsibilities.

(1) The PAH shall afford the FAA or NAA any necessary support in their surveillance activity.

(2) When specifically requested by the FAA/NAA to facilitate surveillance activities, suppliers located outside the U.S. must make appropriate data available to the FAA through the PAH for certificate management purposes in the English language.

NOTE: When the FAA requests the CAA/NAA in a BAA/BASA jurisdiction to conduct surveillance activities or conformity inspection(s) at a supplier facility, the FAA will not be responsible for any charges that the CAA/NAA may impose to accomplish the request(s).

Attachment 1
PAH – Supplier Arrangement

The following list comprises the minimum elements that should be defined in the arrangement between the PAH and the supplier, if applicable (see Note a). Guidance on the content of each element is provided, but this is not intended to be comprehensive.

1. Scope

a. Identify items (see Note b) provided by the supplier and the associated supplier facilities

b. Identify any limitation(s) defined by the PAH

2. PAH evaluation

a. Stipulate that the supplier is acting under the PAH quality system, and all the corrective actions requested by the PAH are to be implemented

3. Implementation procedures

a) Attach a quality plan or equivalent documentation to the contract

4. Internal Quality System

a. Identify methods for the PAH to evaluate the internal quality system of the supplier

b. Describe the interface between the quality systems of the PAH and the supplier in the quality plan

5. Design data and configuration control

a. Identify the design data package provided by the PAH, which includes all pertinent data required for the supplied item(s) to be identified, manufactured, inspected, used and maintained

b. Establish procedures for the management of design changes

6. Manufacturing data

a. Identify the manufacturing data developed by the supplier, if any, based on the design data (see item # 5) submitted by the PAH

7. Test and inspections (including incoming)

a. Identify procedures to define the necessary test and inspection processes:

(1) to ensure and determine conformity of the supplied item(s) during the supplier's manufacturing activities and at receipt by the PAH

(2) to be performed for (re-)qualification of the supplier (including First Article Inspection) and the relating documentation requirements

b. The PAH may rely on inspection/tests performed by supplier, provided that:

(1) personnel responsible for these tasks satisfy the quality standards of the PAH, and

(2) quality measurements are clearly identified, and

(3) the records or reports showing evidence of conformity are available for review and audit.

8. Identification and traceability

a. Stipulate that the PAH ensures flow down, to the supplier and any sub-tier suppliers, of the item(s)' identification and traceability requirements in order to identify the configuration of the item(s) throughout the item(s) life

9. Supplier Personnel Competence

a. Identify the PAH requirements for supplier personnel (i.e., production, inspection, and quality staff) competence, based on qualifications, education, training, skills, and experience

10. Calibration

a. Ensure that calibration is traceable to a national standard that is acceptable to the authority of the PAH

b. Ensure that certificates are submitted where suppliers perform calibration services for the PAH

11. Handling, storage (segregation) and packing

a. Identify requirements from the PAH concerning handling, storage, packing, and shelf-life to be followed by the supplier;

b. Address segregation of approved and non-approved items as well as non-conforming items

12. Record completion and retention

a. Identify procedures for document management and retention by the supplier

13. Non-conformities

b. Identify procedures for the handling and documenting of non-conformities between the PAH and the supplier, addressing the:

(1) identification, documentation, and classification (major, minor, etc.) of non-conformities, and

(2) the disposition of non-conformities and the subsequent segregation and control of the non-conforming articles and materials including the secure disposition of scrap items to avoid reuse (see item # 11).

Note: The disposition of non-conformities is generally the responsibility of the Design Approval Holder. Nevertheless it may be acceptable to the authority that the Design Approval Holder may delegate under its responsibility the approval of non-conformities to persons located in the organization of the PAH and its suppliers, thus acting as part of the Design Approval Holder in this respect.

14. Conformity document

a. Specify the document by which the supplier certifies conformity to the applicable design data to the PAH

15. Provisions for Direct Delivery / Direct Shipment

a. Identify the authorization and the requirements for direct delivery / direct shipment to end users from the supplier's facilities based on relevant regulatory requirements

16. Assistance for continued airworthiness

a. Identify procedures for supplier assistance to the PAH for continued airworthiness, including methods to notify and act upon notification of already delivered non-conforming items, ensuring proper investigation and implementation of corrective action

17. Sub-Tier Suppliers

a. Specify the conditions under which the supplier may sub-contract to or supply from a third party (in some cases specific authorization may be needed, in some others only notification may be sufficient)

b. Specify procedures

(1) for a supplier to flow down the applicable authority and PAH requirements to sub-tier suppliers

(2) for notification to the PAH in case of further sub-tier supplier activity and/or significant problems encountered during manufacturing

18. Significant change to the quality / inspection system

a. Require that the PAH be notified as soon as practical of any changes to the supplier system evaluated by the PAH which may affect the quality of the supply

19. Occurrence reporting system

a. Specify to the supplier the necessary requirements for occurrence reporting to ensure that the PAH can comply with authority requirements for occurrence reporting

20. Access for PAH and PAH authority

a. Ensure the right of access to all involved facilities in the supply chain for the PAH and PAH authority to enable:

(1) the PAH to verify compliance with the PAH–Supplier Arrangement and to assess the quality of the contracted items, and

(2) the authority or its designated agent to investigate the PAH's compliance with the applicable requirements at supplier level.

21. Language

a. Identify the language to be used for the exchange of information (to include all working documents such as technical and quality data), which is acceptable to the PAH authority

22. Identification of Responsibilities

a. Identify responsible office/function/positions in charge for all elements of the PAH-Supplier Arrangement

23. Duration of the Supplier Arrangement

a. Identify the duration of the supplier arrangement in terms of time and/or quantity of supply to be delivered to the PAH

Notes:

a) State in the supplier arrangement whenever one or more of the elements is found to be not applicable by the PAH.

b) The term "item" in this attachment comprises products, articles or appliances as well as consumables, materials, standard parts or services.

Appendix 2
Certifying Staff

1. PURPOSE. This appendix provides information and describes criteria for establishing and maintaining a certify staff. Production Approval Holders may use this document in support of their responsibilities under §§ 21.146, 21.316, and 21.616 for the issuance of an airworthiness approval for each aircraft engine, propeller, and article, produced under their production approval, that conforms to its approved design and is in a condition for safe operation.

2. DEFINITION. For the purposes of this appendix, a certifying staff is defined as those individuals authorized under a PAH's quality system to issue an airworthiness approval. The important concept behind the new certifying staff regulatory provision is that the FAA will not approve these individuals directly. Rather, the FAA will approve and monitor a system (e.g., procedures, processes, or methods) developed by a PAH for the selection, appointment, training, termination, record keeping, and management of these individuals.

3. BACKGROUND, KNOWLEDGE, AND EXPERIENCE. In the past, the function of issuing an airworthiness approval was performed either by the FAA or its appointed part 183 designees. Changes in part 21 have moved those responsibilities from the FAA and its designees to the PAH. The certifying staff will be expected to comply with all 14 CFR requirements and FAA policy with regard to the issuance of an airworthiness approval. The PAH's selection and appointment records should show that the individual's background, knowledge, and experience demonstrate his or her integrity and ability to apply sound judgment. In selecting and appointing individuals, those individuals need to be knowledgeable of the FAA regulations, policies, and procedures; and have technical experience and skills commensurate with the complexity of the product or article for which an airworthiness approval is to be issued. The knowledge, experience, skill, and training requirements used by the FAA to appoint its 14 CFR part 183 designees is acceptable for certifying staff.

4. ELEMENTS OF A CERTIFYING STAFF PROGRAM. The PAH's FAA-approved quality manual should maintain a current listing of all authorized certifying staff members. This listing should list each certifying staff member by name, function(s), scope or limitations, and location at which their functions are to be conducted. The PAH's certifying staff program procedures should, as a minimum, address the following:

a. Identification of the person, or position, within the quality system that is responsible for establishing and maintaining the company's certifying staff program.

b. A process for determining the number of individuals needed to support the company's workload.

c. The specific functions, product, article and location(s) where the services of a certifying staff member will be needed. This would include both PAH facilities or approved supplier locations within or outside the United States.

d. The general knowledge, type and length of experience, and technical qualifications requirements needed for a specific function, product or article.

e. Training and testing requirements (curriculum), to include both initial and on-going, and the frequencies.

f. The continuous oversight/monitoring of all certifying staff and their activities, regardless of location. This includes, for example, the scope of the oversight and its frequency.

g. Methods for maintaining adequate records for each certifying staff member. This includes establishing a record retention period. The records should, as a minimum, contain the following information for each selected individual:

(1) Name.

(2) Date of birth.

(3) Experience.

(4) Training status/completed courses.

(5) Scope of the authorization.

(6) Location(s) at which functions are to be conducted.

(7) Date of authorization.

(8) Appointment status.

(9) Expiration date of authorization, as appropriate.

(10) Removal of authorization for cause.

(11) Identification number of authorization, as appropriate.

h. Method for the withdrawal of an authorization.

i. Evidence of authorization. The method used should make it very clear to the PAH, the certifying staff member, and the FAA, who is authorized as a certifying staff member and the overall scope and limitations of their authorization.

j. Removal/termination of authorization.

k. Method for self-auditing of the effectiveness of the overall certifying staff program.

l. Retention period for records related to the issuance of each airworthiness approval (e.g., FAA Forms 8130-3, 8100-1, shipping documents, etc.).

Appendix 3
Scrap or Salvageable
Aircraft Products and Articles

1. PURPOSE. The information provided in this appendix may be used by Production Approval Holders, and their suppliers, hereafter referred to as the manufacturer. This information may be applied to manufacturers involved in the control, distribution, sale, maintenance, or disposition of scrap or salvageable aircraft engines, aircraft propellers, and aircraft articles (hereafter referred to as "products and articles"). This information may also be used to identify, segregate, and control rejected products and articles in order to preclude their use in finished product.

2. BACKGROUND. Products and articles may be deemed scrap or salvageable once determined unserviceable or ineligible for installation on an aircraft, aircraft engine, or aircraft propeller. In some cases, it has been common practice to dispose of scrapped products and articles by selling, discarding, or transferring the items. A lack of proper industry controls may result in an article being copied or repaired and reintroduced into the market falsely identified as an approved article. Use of such products and articles can have serious safety implications and liabilities for the manufacturer, aircraft operator, or repair facility. The use of an effective system to control scrap or salvageable products and articles will reduce the potential for these items being distributed or sold as serviceable.

3. DEFINITIONS. For the purposes of this appendix, the following definitions apply to the discussion in this document and may not be the same as similar terms used in other documents or applications:

a. Salvageable. Aviation products and articles that are unserviceable (or of unknown status) from an economic point of view, but have a potential value in an aviation application. Salvageable products and articles are placed into two categories:

(1) Non-airworthy products and articles that may be worth storing until they can be restored to an airworthy condition, or until shown to be airworthy with adequate documentation and/or testing.

(2) Products and articles that cannot be found airworthy at the time they are stored, but which there is reason to believe that they are likely to have future aviation value. Examples are:

(a) A product or article that has reached its present life limit, but which may receive an increase in that limit based on in-service experience and analysis.

(b) A product or article that requires a repair for which there is currently no approved repair process, but for which a new approved process may be anticipated.

b. Scrap. Products and articles that the owner has decided to dispose of because they are beyond economical repair, considered to be of little value, or unusable for any other aviation reason. Scrap products and articles are placed into four categories:

(1) Products and articles that were used in safety-critical aviation applications and may have future use in non-aviation applications.

(2) Products and articles that were used in low-risk safety aviation applications and may have future use in non-aviation applications.

(3) Products and articles whose misuse in aviation poses an insignificant safety risk.

(4) Products and articles that have no value except for the base material.

4. DOCUMENTING THE PROCESS. Maintaining a well-defined quality program is fundamental to controlling rejected products and articles. One element to be addressed within this program is the control and disposal of scrap and salvageable products and articles. Quality systems without this element could allow products and articles to migrate back into the active inventories.

5. PREVENTING MISREPRESENTATION OF SCRAP PRODUCTS AND ARTICLES. Manufacturers should dispose of scrap products and articles through mutilation, when appropriate. Proper and thorough mutilation of products and articles will ensure they are unusable for their original application and render them incapable of being reworked or camouflaged to provide the appearance of being serviceable. Effective mutilation may be accomplished by one or a combination of the following methods: Grinding; burning; removal of a major integral feature; permanent distortion of products and articles; cutting a significant size hole with a cutting torch or saw; melting; sawing into many small pieces; and removing manufacturer identification, part, lot, batch, and serial number.

6. DISPOSING OF SCRAP PRODUCTS AND ARTICLES. Manufacturers disposing of scrap products and articles may choose to release them for legitimate non-flight use. This non-flight usage may include training, education, research and development, tool set-up, or non-aviation applications. In such instances, mutilation may not be appropriate. The following methods may be used to prevent future misrepresentation:

a. PERMANENTLY AND CLEARLY mark the products and articles as “NOT FOR AVIATION USE” and “NOT SERVICEABLE.” Ink stamping is not normally considered an acceptable method unless indelible ink is used, and the products and articles are checked to ensure that the ink cannot be removed.

b. Remove part number identification.

c. Remove identification plate and marking.

d. Maintain a tracking or accountability system by serial number or other individualized data to record transferred scrap products and articles.

e. In any agreement or contract transferring scrap products and articles, develop written procedures identifying disposition and disposal requirements.

f. Secure a signed certification statement from the purchaser indicating that “the purchaser will not use or convey these products and articles for use in aviation products.”

For those items determined to be scrap and having no further aviation use, manufacturers should have procedures that require documentation such as a written contract with scrap dealers indicating their

intent to properly dispose of all products and articles received. These procedures should also require that the manufacturer ensures scrap dealers follow their contractual requirements. Manufacturers should maintain records of serial numbers for scrapped life-limited or other critical products and articles. In such cases, the owner who mutilates applicable products and articles is encouraged to provide the original manufacturer with the data plate or serial number and final disposition of the product or article.

7. PREVENTING MISREPRESENTATION OF SALVAGEABLE PRODUCTS AND ARTICLES.

Manufacturers handling salvageable products and articles should establish secure areas to segregate such items from active serviceable inventories and prevent unauthorized access. Furthermore, manufacturers should develop procedures to address the retention of records that indicate the status of products and articles that exceed current repair criteria and life limits, and are being held in anticipation of future repair methods or extension to life limits. Caution should be exercised to ensure that these products and articles receive the appropriate final disposition.

Aviation safety is best served with sound processes that control scrap and salvageable products and articles. Utilizing the practices identified in this document will reduce the potential for these items being distributed and sold as serviceable products. With aviation safety in mind, the aviation community is responsible for preventing misrepresentation of aviation products and articles. The FAA encourages manufacturers to establish a program that controls scrap and salvageable products and articles as an integral part of their quality management systems.

Misrepresented products and articles that are offered for sale, or have been furnished for aviation use, should be reported to the FAA. This may be accomplished via FAA Form 8120-11, SUP Notification Form, or by calling the Aviation Safety Hotline toll free number, 800-255-1111. Further information may be found on this subject in Advisory Circular 21-29, Detecting and Reporting Suspected Unapproved Parts. A copy of this AC may be obtained from http://www.faa.gov or by mail. Send written request to:

U.S. Department of Transportation
Subsequent Distribution Office, SVC-121.23
Ardmore East Business Center
3341Q 75th Avenue
Landover, MD 20785

Appendix 4
Internal Audit Program

1. PURPOSE. This appendix provides information and describes criteria for establishing an internal audit program. This appendix may be used by Production Approval Holders and their suppliers to show compliance with § 21.137 with regard to internal audits.

2. DEFINITION. For the purposes of this appendix, an internal audit program is a comprehensive, continual monitoring process that is initiated and usually managed by top company and quality assurance (QA) management. The personnel conducting the various audits in support of the internal audit program may be internal or external to the process. The objective of this process is to promote attitudes and procedures that focus on controlling processes, rather than depending on corrections of deficiencies, to meet quality goals.

3. ELEMENTS OF AN INTERNAL AUDIT PROGRAM. An internal audit program should be part of the overall quality system, be approved by top company and QA management, and have a detailed written description of the key elements of the program. Each PAH is unique with regard to size, facilities, personnel, resources, and methods of operation. Therefore, different types of programs may be appropriate for individual organizations. The three basic audit programs commonly used are: (1) a dedicated internal quality audit department; (2) a dedicated individual manager with part-time auditors provided from throughout the organization; and (3) a combination of internal and external resources. The most critical elements of an audit program are: (1) an adequate level of independence; (2) a reporting process that ensures an accountable manager is aware of the audit results; and (3) an effective corrective action process to determine root cause, correct deficiencies, and prevent recurrence of deficiencies. The program should have a structure and process designed to improve all system elements/processes that affect product quality. The key elements of an internal audit program are:

a. Audit Planning.

(1) Audit Schedules. Specific audit schedules should be developed to identify areas/activities subject to audit and assure they are audited in a predetermined frequency and defined timeframe. Audit schedules should be based on the criticality of the activity being audited, with consideration to factors such as audit result history, production volume, process performance, high-risk areas, and management concerns.

(2) Auditor Selection. The internal quality audit program should specify that evaluators receive training in auditing, audit principles, and systems analysis techniques. When full-time dedicated audit resources are not practical, developed procedures should show that persons performing audits or supervising audit teams do not have direct responsibility for the areas being audited.

(3) Audit Preparation. Auditor needs to be cognizant of internal requirements, external requirements, and other factors that may impact the process.

(4) Checklist Development. A thorough audit program will be designed to determine and evaluate how an organization's quality manual, operating procedures, process controls, methods, and practices account for and incorporate all internal and external requirements. In essence the checklist questions are the transposition of a standard, regulation, or procedural requirement into a series of

questions, denotes points to be checked and helps the auditor determine the correct order in which to proceed with an audit.

b. Conducting the Audit. The audit checklist should be used by the auditor to gather evidence to determine compliance or noncompliance to the quality system and/or standard being evaluated. Evidence is gathered via review of articles, documents, observation of activities, record checks, and interviews with key individuals in the area(s) under review. Evidence gathered during the audit should be documented as the audit is conducted.

c. Reporting the Results. A report should be prepared documenting the results of the audit. Procedures should be in place that allows straight-line reporting of the audit team to top company and QA management. The audit report should include, at a minimum:

(1) Date the audit was conducted.

(2) Auditor performing the audit.

(3) Standard/procedure the audit was conducted against (i.e., part 21, internal procedure, etc.).

(4) Summary of findings, including brief descriptions of the findings and supporting references to related procedures, records, etc.

(5) Evaluation and relative importance of a finding (i.e. major or minor).

(6) Summary of observations, both positive and negative.

d. Root Cause/Corrective and Preventative Action. The PAH should determine root cause and develop a corrective and preventative action plan.

e. Close the Audit Findings. After indication of completion from the process owner, QA management should verify that the process changes were effective in correcting the existing deficiency and preventing recurrence. If the verification process indicates that the corrective action was not effective, top company management should be notified, and QA management should request additional corrective action and revalidation from the process owner.

f. File Report. Audit reports, including corrective action and closure data, should be maintained.

Appendix 5
Production Certification
Multinational/Multi-Corporate Consortia

1. PURPOSE. This appendix provides information and describes criteria to be emphasized in evaluating and approving the quality system of a multinational and/or multi-corporate consortium seeking a production certificate (PC). This appendix would not apply to a type certificate holder who enters into a licensing agreement with a manufacturer who, at the time of license, holds a PC. The FAA would not consider such a licensing arrangement the formation of a PC. Production certificate extensions are addressed in AC 21-24, Extending a Production Certificate to a Facility Located in a Bilateral Airworthiness Agreement Country.

2. BACKGROUND. Agreements to form a consortium for the co-production of aviation products are a new trend in the aviation industry. Such a consortium may be composed of multiple entities, including companies from outside the United States and domestic companies. The FAA has received a number of applications for PCs from consortium companies.

3. DEFINITION. For the purposes of this appendix, a multinational/multi-corporate consortium consists of a group of U.S. manufacturers and manufacturers located outside the U.S. who have agreed to form a single company for production of a particular product. A consortium company usually exists in name only, in that it does not physically manufacture a product in one location. The consortium company will retain responsibility for the design and quality of the product for which the PC has been issued, but may assign the manufacturing task to other partner companies or suppliers located domestically or in combination with manufacturers located outside the United States.

4. QUALITY SYSTEM.

a. Section 21.137 requires applicants for a PC to demonstrate that they have established and can maintain a quality system for their product, so that each article will meet the design provisions of the pertinent type certificate. The FAA considers the consortium company to be the PC applicant, and the partner companies to be suppliers. The consortium company will be named on the PC, along with the consortium company address (possibly a corporate office) and the address(es) of the principal and subordinate manufacturing facilities. Extension of a PC to facilities located outside of the United States may be authorized when certain criteria are met, as listed in AC 21-24. If a PC is extended to a facility located outside the U.S., certificate management responsibility remains with the FAA.

b. In the case of multinational/multi-corporate consortia, the fact that a partner company or supplier may have an FAA approved quality system in place for its own product does not affect the requirements for the PC applicant to have an independent quality system which meets the requirements of § 21.137.

c. A PC applicant functioning in reality as a corporate entity, a distributor, or an assembler, shall have a viable means of ensuring that all articles, processes, procedures, and completed products are properly inspected for conformity to the approved type design.

5. QUALITY SYSTEM DOCUMENTATION.

a. The applicant for a PC must establish to the FAA's satisfaction that its quality system and procedures meet the requirements of § 21.137 before a PC is issued.

b. The quality system data must clearly specify that all facilities, domestic and those outside the U.S., will be made accessible to the FAA and to the Civil Aviation Authorities (CAA) when acting on behalf of the FAA. If articles or services are provided by a supplier/manufacturer in a country outside the U.S., accessibility would include review of the data, i.e., drawings, specifications, procedures, inspection records, etc., and equipment pertinent to the articles produced under the PC.

c. The quality system manual proposed by the applicant must contain sufficient details to establish the quality system organization and its procedures as a separate and independent entity, rather than simply incorporating by reference the quality systems of its partner companies. This does not preclude the use of, or reference to, applicable portions of a partner company's quality system, but ensures that the applicant's system will be evaluated on its own merits. This also enables the FAA to conduct surveillance to ensure compliance with the regulations.

6. QUALITY ORGANIZATION AND AUTHORITY.

a. The applicant's top quality manager must have direct access to the consortium's top management.

b. The applicant's quality system organization must have an independent management organization which establishes the departmental control in quality matters over the partner companies with respect to the jointly produced product. The individuals chosen to fill these management positions must have a clearly defined and separate allegiance to the applicant's top management, rather than to any previous company they may have been employed by or are presently working for.

c. The responsibility and authority of the employees in the consortium's management organization, including their relationship to the quality and production organizations of the partner companies, must be clearly defined in the quality system data.

d. The applicant may propose to assign inspection authority for ensuring the quality of products being produced to a limited number of its employees. While no minimum number of employees can or should be specified by the FAA, the viability of the proposed quality system procedures shall be assessed with respect to the number of employees available to implement it.

e. It is particularly important to establish accountability for compliance with § 21.137 in the case of a multinational consortium, in that responsibilities of suppliers outside the U.S. for their other products under their own civil airworthiness authorities may be inconsistent with those required by § 21.137. Compliance responsibility for the consortium product will rest with the PC holder. This direct responsibility will be understood by the applicant's management and the management of the supplier, and be described in the quality manual.

f. The fact that the actual manufacture of the applicant's product may take place in a country outside the U.S. will not affect the applicability of FAA regulations and orders pertaining to management and surveillance of the PC holder.